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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/000,452 | 12/04/2001 | Michael McGrogan | LAY-007ORD | 9215 |
| 51951 | 7590 | 06/06/2006 | EXAMINER | |
| THE LUTHER LAW FIRM 12198 E. COLUMBINE DR. SCOTTSDALE, AZ 85259 | | | | HAYES, ROBERT CLINTON |
| ART UNIT | | PAPER NUMBER | | |
| | | 1649 | | |

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/000,452 | MCGROGAN ET AL. |
| | Examiner | Art Unit |
| | Robert C. Hayes, Ph.D. | 1649 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10, 14, 17, 19, 20 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 14, 17, 19, 20 and 24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-10, 14, 17, 19, 20 and 24 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/23/02, 3/16/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-10, 14, 17, 19, 20 & 24) in Paper No. 3/06/06 is acknowledged, along with cancellation of all non-elected claims 11-13, 15, 16, 18, 21-23 & 25-27. Thus, Applicant's election of Group I in the reply filed on 3/06/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In addition, because it appears that Applicant's invention is now only directed toward methods of producing a population of differentiated dopaminergic neuronal cells, methods of improving survival of dopaminergic neuronal cells or producing neurotransmitter/ dopaminergic phenotype cells will not be further restricted into other distinct neurotransmitter phenotype groups, unless later claimed as such (i.e., as it relates to serintinergic, cholinergic and gabanergic cells). Therefore, claim 24 should be amended to reflect only the elected invention of producing dopaminergic cells. It is further noted that the specification fails to disclose any methods of producing any different neuronal cell type using lithium, etc.

Information Disclosure Statement

2. The information disclosure statement filed 3/16/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of preparing human differentiated TH/dopaminergic neurons suitable for treating Parkinson's Disease, does not reasonably provide enablement for methods of preparing such cells wherein the method involves preparing dopaminergic cells in the presence of glioma cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Simply put, glioma cells present in any transplanted tissue would kill the Parkinson's patient; thereby, preventing one skilled in the art from determining whether or not the transplanted TH-positive neurons actually were "suitable" for "treating Parkinson's Disease". Thus, claim 20 is not enabled for producing differentiated TH/dopaminergic neurons "suitable for treating Parkinson's Disease" when co-cultured in the presence of glioma cells.

4. Claims 1-10, 19-20 & 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of what constitute “an [unknown] inducing agent”, for “*minimally replating* [under what specific conditions] with *an* [unknown] *inhibitor* to *optimize* [what and how] the dopaminergic phenotype”, “at least one cell type which stabilizes or improves the *dopaminergic phenotype* of the cells”, and “at least one *indicator* of neuronal differentiation” are unknown and ambiguous since none are specifically recited in the claims (i.e., as it relates to claims 1, 7, 19 & 24). Note that claim 24 is examined as it relates to producing only dopaminergic cells. Therefore, “desired” neuronal type or “desired” phenotype should also be specified to reflect such, in order to avoid making claim 24 ambiguous.

5. Claims 14 & 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No method step is provided for when “improving survival of human neuronal cells...”, as recited in the preamble, is accomplished.

Claim 17 is dependent on claim 15, which is not a method claim, unlike claim 14.

6. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the phrase “including” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 19 & 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Boss et al. (US Patent 5,411,883; IDS Ref #1).

Boss et al. teach isolation of human and porcine neuron stem and progenitor cells (e.g., mammalian brain-derived neuronal tissue from the mesencephalon; cols. 3-7; as it relates to claims 1-5) that inherently “lack at least one indicator of neuronal differentiation”. In that page 4 of the specification defines “NT2 cells” as “undifferentiated precursors”, the cells recited in claim 4 are identical to Boss’ progenitor cells; absent evidence to the contrary. Columns 6-9 describe dissection, isolation of progenitor cells and proliferation of progenitor cells, which includes co-cultures with any remaining fetal stem cells derived from the fetal mesencephalon (i.e., as it relates to claims 7-8). Partial differentiation, full differentiation and selecting individual cells expressing dopaminergic markers, such as TH, are described in columns 13 & 19-20, which includes use of cAMP, retinoic acid, or the mitotic inhibitor, dbc-AMP, etc. (i.e., as it relates to claims 1, 10, 19 & 24), and in which additional “inhibitors”, such as phosphodiesterase inhibitors are also described in col. 13 (i.e., as it relates to claims 1 & 24). Proliferating the neural cells in fresh minimal F12 medium + either 5% fetal cord serum or 5% Chang’s supplement C, in which either medium inherently contains growth factors or

dopaminergic-specific "inhibitors" to "optimize" the dopaminergic phenotype, further meets the limitations of claims 1 & 24. Moreover, continued culturing of these differentiated dopaminergic cells in the presence of the inhibitor 5 mM dbc-AMP for one week resulted in more catecholamine production and different proportions of catecholamine production, as determine by HPLC analysis (i.e., a "dopaminergic phenotype" marker; col. 20; as it relates to claims 1, 19 & 24).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-7997 (toll-free).



Robert C. Hayes, Ph.D.
May 15, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER